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(54) Guide wire for catheter

Führungsdraht für Katheter

Fil de guidage pour cathéter

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(56) References cited:
EP-A- 0 073 308
FR-A- 1 599 564
US-A- 3 757 768
US-A- 4 037 324
WO-A-83/01575
GB-A- 1 435 797
US-A- 3 789 841

- Encyclopaedia of Chemical Technology, 3rd Ed, Vol.20; Wiley, New York etc., pp.726-736;

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Description

This invention relates to a guide wire for a catheter for making the catheter guidable, and more particularly to a guide wire for a catheter for making the catheter for the medical treatment of tests introducible to a predetermined position in a blood vessel, digestive duct, trachea, other body cavities or the like and retainable thereat.

Conventional guide wires for a catheter, for example the guide wire for a catheter known from the EP—A—0 073 308, have a constant diameter over the total length thereof and are formed of plastic coated stainless steel wire. This kind of guide wire, however, is subject to a number of deficiencies which, in the following, shall be described in detail.

As typified in the case of retaining the Angiographic Catheter at a predetermined position in a blood vessel, in many cases, the aforesaid guide wire is percutaneously inserted into the blood vessel by use of an introducing needle, the distal tip opening portion of the catheter is covered onto a proximal end portion of the guide wire disposed outside of a human body, and the catheter is inserted into the blood vessel with the guide wire being utilized as an arbor. Therefore, a certain level of rigidity is given to the body portion of the aforesaid catheter so that the guide wire is made smoothly insertable into the blood vessel against a resistance generated between the outer surface of the guide wire and the tissues of the human body and the catheter is made guidable against a resistance generated between the outer surface of the guide wire and the inner surface of the catheter.

However, as described above, since the body portion of the conventional guide wire is made of the general metallic material, plastic deformation is caused to the body portion when a certain value of displacement is exceeded, the guide wire may be buckled depending on the skill in manual operation, whereby the buckled portion may be turned into an unrestorable deformed portion, and this deformed portion forms a considerable obstruction against the advance of the catheter, so that difficulties are felt for an operation of smoothly introducing the catheter. Furthermore, in the case of guiding the catheter by previously curving the distal end portion of the catheter so that the catheter can be readily inserted into the predetermined position in the blood vessel, the catheter is covered onto the guide wire and comes into the state of being straightened. Hence, the resistance of the catheter covered onto the guide wire is increased, whereby a possibility of occurrence of a trouble caused by the aforesaid buckling is increased.

In order to have the catheter reach the predetermined position of the blood vessel after the catheter together with the guide wire have been inserted into the blood vessel, it is necessary to further advance in the blood vessel the distal end portion of the guide wire projected a predetermined length from the distal end opening of the catheter. Therefore, the distal end portion of the conventional guide wire need to have such a flexibility that the guide wire does not damage the wall of blood vessel, adapts itself to the shape of meandering blood vessel, and is insertable into a complicated vascular branching.

However, as described above, since the distal end portion of the conventional guide wire is made of a general metallic material, plastic deformation is caused to the distal end portion when a certain value of displacement is exceeded, whereby the flexible movability of the guide wire for reaching a predetermined position in the blood vessel is endangered. Furthermore, even if the distal end portion of the guide wire reaches the predetermined position in the blood vessel, the distal end portion is lowered in its rebound due to plastic deformation. Hence, while the forward end portion of the catheter is being advanced, there is no resistance between the distal end portion of guide wire and the wall of blood vessel, which is required for retaining the forward end portion of the guide wire against the flexure stress of the catheter, with the result that the distal end portion of the guide wire is drawn out of the predetermined position of the blood vessel, and, in many cases, the retention of the guide wire at the predetermined position ends in a failure and much time is wasted for the manual operation. There too has been proposed the distal end portion of the guide wire to be deformed into a J-shape so as to prevent the wall of blood vessel from being demaged and the distal end portion of the guide wire from engaging the wall of blood vessel during its movement in the blood vessel. However, the distal end portion of the guide wire of the type described never fails to be deformed into a rectilinear shape while it passes through the introducing needle. Hence, thereafter, the distal end portion of the guide wire is not restored to a perfect J-shape, and, in many cases, such a disadvantage is presented that the initial function is not satisfactorily fulfilled.

It is the object of the present invention to provide a guide wire for a catheter making the catheter reliably and readily introducible to a predetermined position, the guide wire further

being capable of being restored to the original state, even if the guide wire buckles,
having the distal end portion flexible enough to be insertable, even when a complicated vascular system is encountered and having a good restoring force against deformation, and
having a distal end portion which constantly has a suitable rebound and may be retained at a predetermined position when it guides the catheter.

This object is attained by the characterizing features of claims 1 and 3, advantageous embodiments of the invention being given by the sub-claims.

The advantages obtained by the invention shall be described in more detail with reference to the drawings.

Fig. 1 is a plan view showing a first embodiment of the guide wire for a catheter according to the present invention;

Fig. 2 is a cross sectional view taken along the line II—II in Fig. 1;

Fig. 3 is a cross sectional view taken along the line III—III in Fig. 1;

Fig. 4 is a cross sectional view taken along the line IV—IV in Fig. 1;

Figs. 5(A) through 5(D) are plan views showing modifications of the forms of the distal tip portion of the guide wire according to the present invention;

Figs. 6(A) and 6(B) are plan views showing modifications of the forms of the distal end portion of the guide wire according to the present invention;

Figs. 7 and 8 are graphic charts showing the flexure load-displacement value characteristics of the super-elastic metallic member and the general elastic metallic member;

Fig. 9 is a schematic diagram showing the state of use of the guide wire according to the present invention;

Fig. 10 is a plan view showing a second embodiment of the guide wire for a catheter according to the present invention;

Fig. 11 is a cross sectional view taken along the line XI—XI in Fig. 10;

Fig. 12 is a cross sectional view taken along the line XII—XII in Fig. 10;

Fig. 13 is a cross sectional view taken along the lines XIII—XIII in Fig. 10;

Figs. 14(A) and 14(B) are plan views showing modifications of the forms of the distal tip portion of the guide wire according to the present invention;

Figs. 15(A) and 15(B) are plan views showing modifications of the distal end portion of the guide wire according to the present invention;

Figs. 16 and 17 are graphic charts showing the flexure load-displacement value characteristics of the super-elastic metallic member and the general elastic metallic member;

Fig. 18 is a graphic chart showing the flexural rigidity-maximum outer diameter characteristics of the guide wire; and

Fig. 19 is a schematic diagram showing the state of use of the guide wire according to the present invention.

Fig. 1 is a plan view showing the first embodiment of a guide wire 10 for a catheter according to the present invention. Figs. 2 through 4 are cross sectional views taken along the lines II—II to IV—IV in Fig. 1.

The guide wire 10 have a body portion 11 comparatively high in rigidity and a distal end portion 12 comparatively flexible, and a tapered portion 13 disposed therebetween.

The aforesaid guide wire 10 is generally formed of a super-elastic (pseudo-elastic) metallic member such as a TiNi alloy of 49~58 atom%, a Cu-Zn alloy of 38.5~41.5 wt% Zn, a Cu-Zn-X alloy of 1~10 wt% X (X=Be, Si, Sn, Al or Ga), an Ni-Al alloy of 36~38 atom% Al, or the like.

In the body portion 11 of the guide wire 10, the outer diameter was determined to be 0.89 mm, the length 130 cm, and the yield stress then in a range between 10 and 80 Kg (Strograph® M type produced by Toyo Seiki K. K., the above-mentioned values were obtained under the conditions of a distance between the chucks being 80 mm, a speed of 5 mm/min and a tension temperature of 22°C). The restoring stress (the yield stress under no load, indicated by B in Fig. 7) was determined to be 60 Kg/mm^2 (22°C) or less. Additionally, the outer diameter of the body portion 11 may be determined to be in a range between 0.1 and 2 mm, and preferably be in a range between 0.45 and 1.15 mm. The length of the body portion 11 may be determined in a range between 10 and 300 cm. As for the distal end portion 12 of the guide wire 10, the outer diameter thereof is determined to be 0.2 mm, the length 20 cm, the yield stress in a range between 10 and 80 Kg/mm^2 and the restoring stress in a range between 0 and 60 Kg/mm^2 or less. Additionally, the outer diameter of the forward end portion 12 may be determined to be in a range between 0.05 and 1.5 mm, and preferably be in a range between 0.1 and 0.5 mm (provided not exceeding the outer diameter of the body portion 11). Furthermore, the length of the distal end portion 12 may be determined to be in a range between 1 and 50 cm, preferably be in a range between 2 and 30 cm. The yield stress at the distal end portion in the embodiment was determined to be in a range between 18 and 24 Kg/mm^2 and the restoring stress in a range between 12 and 18 Kg/mm^2.

The distal tip portion 14 of the distal end portion 12 of the guide wire 10 is formed into a R-shape in order to prevent it from piercing the wall of blood vessel. Furthermore, the tapered portion 13 is progressively reduced in cross-section from the body portion 11 toward the distal end portion 12, whereby the rigidity in a connecting portion between the body portion 11 and distal end portion 12 is moderately varied, so that breakage and bending of the guide wire 10 in this connecting portion can be prevented from occurring.

In order to prevent the distal tip portion of the distal end portion 12 of the guide wire 10 from piercing the wall of blood vessel, the shape of the distal tip portion need not necessarily be limited to the R-shape, but, may be formed into a spherical shape designated by 15 in Fig. 5(A), a J-shape denoted by 16 in Fig. 5(B), a coil-shape indicated by 17 in Fig. 5(C), a ring-shape designated by 18 in Fig. 5(D) or the like.

As shown in Figs. 6(A) and 6(B), the distal end portion 12A and 12B of the guide wire 10 may be curvedly formed into predetermined shapes similar to the vascular system or vascular branching, so that the distal end portions can be reliably and readily inserted into predetermined positions in the blood vessel.

The connecting portion between the body portion

11 and the distal end portion 12 of the guide wire 10 need not necessarily be formed into the tapered shape, but such a cross-sectional shape may be adopted that no considerable change in cross-section occurs between the body portion 11 and the distal end portion 12, or the connecting portion may have an outer diameter intermediate in size between the body portion 11 and the distal end portion 12.

Fig. 7 is a graphic chart in which the flexure load (W)-displacement value (D) characteristics of a TiNi alloy forming a cantilever beam of an outer diameter of 0.6 mm and a length of 20 mm is indicated by solid lines, and the flexure load-displacement value characteristics of a stainless steel wire forming a cantilever beam of an outer diameter of 0.45 mm and a length of 20 mm is indicated by broken lines. Fig. 8 is a graphic chart in which the flexure load-displacement value characteristics of a TiNi alloy forming a cantilever beam of an outer diameter of 0.1 mm and a length of 20 mm is indicated by solid lines, and the flexure load-displacement value characteristics of a stainless steel wire forming a cantilever beam is indicated by broken lines. In Figs. 7 and 8, designated at E is a residual plastic strain value of the stainless steel wire. More specifically, according to Figs. 7 and 8, the super-elastic metallic member (1) is high in restorable elastic strain to reach several % to ten-odd %, and (2) has the characteristics of that, even if the strain is increased, the load is not varied in value. In consequence, the body portion 11 of the guidewire 10 is formed of the super-elastic metallic member having the flexure load-displacement value characteristics substantially equal to that indicated by the solid lines in Fig. 7, whereby the body portion 11 is provided with the elastic strain characteristics having a comparatively high buckling strength. Furthermore, the distal end portion 12 of the guide wire 10 is formed of the super-elastic metallic member having the flexure load-displacement value characteristics substantially equal to that indicated by the solid lines in Fig. 8, whereby the distal end portion 12 is provided with elastic strain characteristics capable of being displaced in a comparatively high extent under a given stress and restorable.

Description will hereunder be given of operation of the first embodiment.

The guide wire 10 is of the rectilinear type in Fig. 1, or of various shapes desirably formed near the distal end portions of catheters 20 as shown in Fig. 9. A curv d portion thereof, for example, and inserted into the body portion 11 comparatively high in rigidity, so that the catheter 20 can be smoothly advanced in a blood vessel 21. Furthermore, the guide wire 10 causes the distal end portion 12 thereof to proceed ahead of the distal end portion of catheter 20, so that the distal end portion 12 can guide the distal end portion of the catheter to a predetermined position 22 in the blood vessel.

Here, the guide wire 10 is provided in the body portion 11 thereof with an elastic strain characteristics comparatively high in yield stress. In consequence, even if a comparatively high flexural deformation is caused to the body portion 11 when the guide wire 10 is inserted into the blood vessel, the guide wire 10 does not reach the plastic deformation region and is not subjected to buckling, so that the buckling, limit of the body portion 11 can be improved. More specifically, even if a deformation of a high value is caused to the body portion 11 by the manual operation applied to the guide wire 10, a portion subjected to this deformation can be readily straightened again, so that no resistance is caused to the advance of the catheter. Furthermore, when the catheter provided at the distal end thereof with the curved portion is covered while being straightened, no resistance of a considerable value occurs between the catheter and the body portion 11, so that the catheter can smoothly advance.

Furthermore, the guide wire 10 is provided at the distal end portion 12 thereof with an elastic strain characteristics capable of being displaced to a comparatively high extent under a given stress and restorable. In consequence, while the distal end portion 12 goes through a bent portion of the blood vessel, a flexural deformation of a high value can be obtained under a load of a comparatively low value, a curved deformation and its restoration are repeated, whereby the accommodation in shape of the guide wire 10 to the meandering blood vessel is improved and the guide wire 10 can be comparatively easily curved according to a vascular branching, so that the guide wire 10 can be smoothly advanced to a predetermined position in the blood vessel. Additionally, when the catheter is inserted to a predetermined position in the blood vessel, the guide wire 10 is provided at the distal end portion 12 thereof with a rebound enough to generate a resistance against the wall of blood vessel, which is required for retaining the guide wire 10 at the predetermined position against the flexure stress of the catheter. As the result, the distal end portion 12 is not drawn out of the predetermined position in the blood vessel and the catheter is suitably retained. Even if the distal end portion 12, which has been previously curvedly deformed, is straightenedly deformed while passing through the introducing needle, the distal end portion 12 is restored to the perfect curved shape, when inserted into the blood vessel thereafter, so that the original function can be fully satisfied.

The guide wire 10 has no irregularities on the surface thereof, whereby the guide wire 10 satisfactorily acts as the blood coagulation and the tensile strength is high as compared with a plastic guide wire, to thereby be safer than the latter.

The guide wire 10 is satisfactory in the torque transmission performance in either one of torsional directions, differing from the conventional coil-shaped guide wire. A torque applied to the body portion 11 makes it possible to reliably and readily direct the distal end portion 12 toward a predetermined position in the blood vessel, so that controllability in inserting the distal end portion 12 to a position in a complicated vascular sys-

tem can be improved.

In addition, in the above embodiment, description has been given of the guide wire 10, in which both the body portion 11 and the distal end portion 12 are formed of the super-elastic metallic member.

Fig. 10 is a plan view showing the second embodiment of the guide wire 30 for a catheter according to the present invention. Figs. 11 through 13 are cross sectional views taken the lines XI—XI through XII—XII in Fig. 10.

The guide wire 30 includes an inner core 31 a coating portion 32, and is constituted by a body portion 30A and a distal end portion 30B.

The inner core 31 of the guide wire 30 is constituted by an inner core portion 31A on the body portion's side and an inner core portion 31B on the distal end portion's side, both of which are integrally formed through a tapered portion 31C. The inner core 31 is generally formed of a super-elastic (pseudo-elastic) metallic member such as a TiNi alloy of 49~58 atom%, a Cu-Zn alloy of 38.5~41.5 wt%, a Cu-Zn-X alloy of 1~10 wt% X (X=Be, Si, Sn, Al or Ga), an Ni-Al alloy of 36~38 atom% Al, or the like.

The coating portion 32 of the guide wire 30 includes a coating portion 32A on the body portion's side and a coating portion 32B on the distal end portion's side. The coating portion 32 is mode of elastomer or a composite material of synthetic resin materials including polyethylene, polyvinyl chloride, polyester, polypropylene polyamide, polyurethane, polystyrene, fluorine plastics and silicone rubber, or an elastomer or a composite material of the above-mentioned plastics, to thereby form a soft, smooth surface with no irregularities thereon. In addition, the coating portion 32 can obtain an anti-coagulating agent such as heparin and urokinase, or through coating of an anti-thrombus material such as silicone rubber, a block copolymer of urethane and silicone (®Avcothane), a copolymer of hydroxyethyl methacrylate-styrene and the like, and can obtain low friction properties by use of resin having a low frictional surface such as fluoro resin and through applying a lubricant such as silicone oil. Furthermore, an X-ray contrast medium made of a single substance of metal such as Ba, W, Bi, Pb or the like, or a compound therebetween is mixed with a synthetic resin material forming the coating portion 32, so that the position of the guide wire 30 in the blood vessel can be accurately determined.

As for the body portion 30A of the guide wire 30, the outer diameter of the inner core portion 31A on the body portion's side is determined to be 0.62 mm, the outer diameter of the coating portion 32A on the body portion's side 0.89 mm, the length 130 cm, the yield stress in a range between 10 and 80 Kg/mm^2 (22°C) (yield stress under load: A in Fig. 17), and the restoring stress (yield stress under no load: 8 in Fig. 17) in a range between 0 and 60 Kg/mm^2 (22°C). In addition, the outer diameter of the inner core portion 31A on the body portion's side determined to be in a range between 0.1 and 1.9 mm, and preferably be in a range between 0.35 and 1.05 mm. The buckling strength is determined to be in a range between 10 and 80 Kg/mm^2 (22°C), and the restoring stress in a range between 0 and 60 Kg/mm^2 (22°C). Additionally, the outer diameter of the coating portion 32A on the body portion's side is determined to be in a range between 0.2 and 2 mm, and preferably be in a range between 0.45 and 1.15 mm. The length of the body portion 30A may preferably be determined to be in a range between 10 and 300 cm.

As for the distal end portion 30B of the guide wire 30, the outer diameter of the inner core portion 31B on the distal end portion's side is determined to be 0.2 mm, the outer diameter of the coating portion 32B on the distal end portion's side 0.47 mm, the length in a range between 0 and 150 mm, and preferably be in a range between 2 and 150 mm, and more preferably be 20 mm, the yield stress in a range between 10 and 80 Kg/mm^2 (22°C). In addition, the outer diameter of the inner core portion 31B on the distal end portion's side is determined to be in a range between 0.05 and 1.5 mm, and preferably be in a range between 0.1 and 0.5 mm, the flexure load in a range between 0.1 and 10 g, and the restoring load in a range between 0.1 and 10 g. Furthermore, the outer diameter of the inner core portion on the distal end portion's side as a whole need not necessarily be limited to the above-described dimensions, but, may partially adopt such dimensions. Further, the restoring stresses of the body portion and the distal end portion need not have the values equal to each other, but it is preferable that the restoring stresses may be varied in accordance with conditions at the heat treatment so as to obtain suitable properties by use of suitable diameters of the wire. In other words, it is preferable to separate the body portion and the distal end portion in heat treatment, so that the restoring stress in the body portion can be high in value and the distal end portion flexible. Then, the diameter of the wire of the inner core on the distal end portion's side is not made too small, so that the mechanical strength thereof can be improved. Furthermore, the outer diameter of the coating portion 32B is determined to be in a range between 0.07 and 2 mm, and preferably be in a range between 0.12 and 1.10 mm. The outer diameter of the forward end portion including the coating portion as a whole need not necessarily be limited to the above-described dimension, but, may partially adopt such dimension. Furthermore, the length of the distal end portion 30B may preferably be determined to be in a range between 1 and 50 cm. The outer diameter of the coating portion may preferably be equal to that of the body portion.

Furthermore, in general, the coating portion 32 is closely fused to the inner core 31 through the above-described synthetic resin member, and a distal tip portion 33 and a rear end portion, i.e., a proximal end portion 36 are solidly secured to each other in the same manner as described above. However, when the coating portion 32 is formed of a hollow tube, in addition to the specific form of closely coating, the guide wire 30 over the total length, it is preferable that the guide wire 30 is

affixed to the inner core 31 through bonding or fusing at the distal tip portion 33 and the proximal end portion 36, or at a suitable position of the body portion of the guide wire 30. In this case, portions of the distal tip portion 33 and the proximal end portion 36 or a portion at the suitable position of the body portion are not substantially over the total length be bonded or fixed to the inner core 31, whereby, when flexed, the guide wire 30 is not restrained by the inner core 31, freely movable relative to the inner core 31, and particularly, flexibly deformable in the distal end portion 30B thereof. In addition, the coating portion according to the present invention may be constructed such that a coating film made of the above-described synthetic resin member is applied to the surface of the inner core 31. In this case also, it is preferable that the coating portion is not solidly secured to at least the inner core portion 31B on the distal end portion's side, so that the distal end portion 30B of the guide wire 30 may be flexibly deformed. The guide wire according to the present invention does not adopt a spring, whereby the form of fixing the coating portion to the inner core is not specified.

The distal tip portion 33 of the distal end portion 30B of the guide wire 30 may be formed into an R-shape in order to prevent it from piercing the wall of blood vessel. Furthermore, the tapered portion 31C is progressively reduced in cross-section from the body portion 30A toward the distal end portion 30B, whereby the ridigity in a connecting portion between the body portion 30A and the forward end portion 30B is moderately varied, so that breakage and bending of the guide arm 30 in this connecting portion can be prevented from occurring.

In order to prevent the distal tip portion of the distal end portion 30B of the guide wire 30 from piercing the wall of blood vessel, the shape of the distal tip portion need not necessarily be limited to the R-shape, but, may be formed into a spherical shape designated by 34 in Fig. 14(A) and a J-shape denoted by 35 in Fig. 14(B).

As shown in Figs. 15(A) and 15(B), the distal end portion 30B of the guide wire 30 is curvedly formed into a predetermined shape similar to the vascular system or vascular branching, so that the distal end portion can be reliably and readily inserted into a predetermined portion in the blood vessel.

The distal end portion 30B of the guide wire 30 may be progressively reduced in diameter toward the distal tip portion 33, so that the distal end portion 30B can be made more flexible.

The connecting portion between the body portion 30A and the distal end portion 30B of the guide wire 30 need not necessarily be formed into the tapered shape, but, such a cross-sectional shape may be adopted that no considerable change in cross-section occurs between the body poriton 30A and the distal end portion 30B, or the connecting portion may have an outer diameter intermediate in size between the body portion 30A and the distal end portion 30B.

This inner core need not nec ssarily be limited to the one formed by a single wire, but, a plurality of wires arranged in parallel to one another or twisted together may be used, so that the above-described function, i.e., a gradual or progressive change in the physical properties may be fulfilled.

Fig. 16 is a graphic chart in which the flexure load (W)-displacement value (D) characteristics of a TiNi alloy forming a cantilever, beam coated by a coating portion made of polyethylene of an outer diameter of 0.89 mm and having an outer diameter of 0.62 mm and a length of 20 mm is indicated by solid lines, and the flexure load-displacement value characteristics of a stainless steel wire forming a cantilever beam coated by a coating portion made of polyethylene of an outer diameter of 0.89 mm and having an outer diameter of 0.45 mm and a length of 20 mm is indicated by broken lines. Fig. 17 is a graphic chart in which the flexure load-displacement value characteristics of a TiNi alloy forming a cantilever beam coated by a coating portion made of polyethylene of an outer diameter of 0.42 mm and having an outer diameter of 0.15 mm and a length of 20 mm is indicated by solid lines, and the flexure load-displacement value characteristics of a stainless steel wire forming a cantilever beam coated by a coating portion made of polyethylene of an outer diameter of 0.42 mm and having an outer diameter of 0.10 mm and a length of 20 mm is indicated by broken lines. In Figs. 16 and 17, designated at E is a residual plastic strain value of the stainless steel wire. More specifically, according to Figs. 16 and 17, the super-elastic metallic member (1) is high in restorable elastic strain, and (2) has the characteristics of that, even if the strain is increased, the load is not varied in value. In consequence, the body portion 30A of the guide wire 30 is formed of the inner core portion 31A made of a super-elastic metallic member having the flexure load-displacement value characteristics substantially similar to that indicated by the solid lines in Fig. 16 and the coating portion 32A made of the synthetic resin material, whereby the body portion 30A is provided with the elastic strain characteristics having a comparatively high buckling strength. Furthermore, the distal end portion 30B of the guide wire 30 is formed of the inner core portion 31B made of the super-elastic metallic member having the flexure load-displacement value characteristics substantially equal to that indicated by the solid lines in Fig. 17 and the coating portion 32B made of the synthetic resin material, whereby the distal end portion 30B is provided with an elastic strain characteristics capable of bing displaced to a comparatively high extent under a given stress and restorable.

Fig. 18 is a graphic chart in which the flexural rigidity (B)-maximum outer diameter (G) characteristics of the guide wire, the inner core portion of which is formed of the super-elastic metallic member and coated by the coating portion made of the plastics, is indicated by solid lines, and the flexural rigidity-maximum outer diameter characteristics of a guide wire formed of only the super-elastic metallic member is indicated by broken lines. According to this Fig. 18, in the guide wire

formed of only the super-elastic metallic member, the range of the maximum outer diameter (Δg1) satisfying the determined flexure rigidity (B1~B2) is small, in contrast thereto, when the inner core 31 is coated by the coating portion 32 as in the aforesaid guide wire 30, the range of the maximum outer diameter (Δg2) satisfying the determined flexural rigidity is enlarged to a great extent, and it is recognized that, when the inner diameter of the catheter to be guided becomes large, the body portion 30A may be formed to have an outer diameter substantially equal to the inner diameter of the catheter, with the flexural rigidity being held within a predetermined range.

Description will hereunder be given of operation of the second embodiment.

The guide wire 30 is of various shapes desirably formed near the distal end portions of the catheters 20 as shown in Fig. 19. A curved portion thereof, for example, is straightened and inserted into the body portion 30A comparatively high in rigidity, so that the catheter 20 can be smoothly advanced in the blood vessel 21. Furthermore, the guide wire 30 causes the distal end portion 30B thereof to proceed ahead of the distal end portion of the catheter 20, so that the distal end portion 30B can guide the distal end portion of the catheter to a predetermined position 22 in the blood vessel.

Here, since the inner core 31 of the guide wire 30 is coated by the coating portion 32, the diameter of the inner core 31 may be made small even when the catheter to be guided is large in its diameter, and there may be obtained an outer diameter of the inner core 31 corresponding to the inner diameter of the catheter to be guided, with the flexural rigidity being held within a predetermined range, so that the catheter can naturally and smoothly dilate the skin and the wall of blood vessel.

In the guide wire 30, the inner core portion 31B on the distal end portion's side and the coating portion 32B on the distal end portion's side are made smaller in cross-section than the inner core portion 31A on the body portion's side and the coating portion 32A on the body portion's side, respectively, whereby the distal end portion 30B is made smaller in cross-section than the body portion 30A, so that the body portion 30A may be provided with the elastic strain characteristics having a comparatively high buckling strength and the distal end portion 30B may be provided with the elastic strain characteristics capable of being displaced to a comparatively large extent under a given stress and restorable.

More specifically, the body portion 30A of the guide wire 30 is provided with the elastic strain characteristics having a comparatively high buckling strength. In consequence, even if a flexural deformation of a comparatively high value is caused to the body portion 30A when the guide wire is inserted into the catheter and the blood vessel, the guide wire 30 does not reach the plastic deformation region and is not subjected to buckling, so that the buckling limit of the body portion 30A can be improved. More specifically, even if a deformation of a high value is caused to the body portion 30A by the manual operation applied to the guide wire 30, a portion subjected to this deformation can be readily straightened again, so that no resistance is caused to the advance of the catheter. Furthermore, when the catheter provided at the distal end thereof with the curved portion is crownedly coupled while being straightened, no resistance of a considerable value occurs between the catheter and the body portion 30A, so that the catheter can smoothly advance.

Furthermore, the guide wire 30 is provided at the distal end portion 30B thereof with an elastic strain characteristics capable of being displaced to a comparatively high extent under a given stress and restorable, in consequence, while the distal end portion 30B goes through a bent portion of the blood vessel, a flexural deformation of a high value can be obtained under a load of a comparatively low value, a curved deformation and its restoration are repeated, whereby the accommodation in shape of the guide wire 30 to the meandering blood vessel is improved and the guide wire 30 can be comparatively easily curved according to a vascular branching, so that the guide wire 30 can be smoothly advanced to a predetermined position in the blood vessel. Additionally, when the catheter is inserted to a predetermined position in the blood vessel, the guide wire 30 is provided at the distal end portion 30B thereof with a rebound enough to generate a resistance against the wall of blood vessel, which is required for retaining the guide wire 30 at the predetermined position against the flexure stress of the catheter. As the result, the distal end portion 30B is not drawn out of the predetermined position in the blood vessel and the catheter is suitably retained. Even if the distal end portion 30B, which has been previously curvedly deformed, is straightenedly deformed while passing through the introducing needle, the distal end portion 30B is restored to the perfect curved shape, when inserted into the blood vessel thereafter, so that the original function can be fully satisfied. The guide wire 30 has no irregularities on the surface thereof, differing from the conventional coil-shaped guide wire, whereby the guide wire 30 satisfactorily acts on the blood coagulation and the tensile strength is high as compared with the plastic guide wire, to thereby be safer than the latter.

The guide wire 30 is satisfactory in the torque transmission performance in either one of torsional directions, differing from the conventional coil-shaped guide wire. A torque applied to the body portion 30A makes it possible to reliably and readily direct the distal end portion 30B toward a predetermined position in the blood vessel, so that controllability in inserting the distal end portion 30B to a position in a complicated vascular system can be improved.

As described above, according to the present invention, in the guide wire for the catheter, having the body portion comparatively high in rigidity and the distal end portion comparatively flexible, are formed of the super-elastic metallic member. In consequence, the catheter can be reliably and readily introduced to a pre-

determined position.

According to the present invention, both the body portion and the distal end portion are formed of the super-elastic metallic member, so that the body portion can be provided with the elastic strain characteristics having a comparatively high yield stress and the distal end portion can be provided with the elastic strain characteristics capable of being displaced in a comparatively high extent under a given stress and restorable.

According to the present invention, a portion between the body portion and at least a portion of the distal end portion may be progressively reduced in cross-section from the body portion toward the distal end portion, whereby a change in rigidity in a connecting portion between the body portion and the distal end portion is made moderate, so that breakage and bending of the guide wire in the connecting portion can be prevented from occurring.

According to the present invention, in the guide wire for the catheter, wherein the inner core is constituted by the inner core portion on the body portion's side and the inner core portion on the distal end portion's side inner core as a whole may be coated by the coating portion made of the plastics, and the guide wire has the body portion comparatively high in rigidity and the distal end portion comparatively flexible, the inner core of the body portion and the inner core of the distal end portion are formed of a super-elastic metallic member, and at least a portion of the inner core portion on the distal end portion's side is made smaller in cross-section than the inner core portion on the body portion's side. In consequence, the catheter can be reliably and readily introduced to a predetermined position.

According to the present invention, the outer diameter of at least a portion of the distal end portion including the coating portion may be made smaller in cross-section than that of the body portion, so that the catheter can be reliably and readily introduced to a predetermined position.

According to the present invention, the outer diameters of the coating portion at the distal end portion and the body portion may be made equal to each other, so that blood can be prevented from leaking out when the introducing needle is inserted, and the catheter can naturally and smoothly expand the wall of skin and the wall of blood vessel.

Claims

1. A guide wire for a catheter, having a wire body portion (11) and a wire distal end portion (12) at least a portion of said distal end portion (12) being made smaller in cross-section than said body portion (11) which is comparatively high in rigidity, said distal end portion (12) being comparatively flexible, characterized in that both said body portion (11) and said distal end portion (12) are formed of a superelastic metallic member.

2. The guide wire according to claim 1, wherein an intermediate portion (13) between said body portion (11) and said distal end portion (12) is progressively reduced in cross-section from said body portion (11) toward said distal end portion (12).

3. A guide wire for a catheter having an inner core (31) which is coated by a coating (32) made of plastic, wherein it has a body portion (30A) and a distal end portion (30B), at least a portion of the inner core (31B) within the distal end portion being made smaller in cross-section than the inner core (31A) within the body portion, said body portion being comparatively high in rigidity, said distal end portion (30B) being comparatively flexible, characterized in that the inner core (31A,31B) both within the body portion and within the distal end portion is formed of a superelastic metallic member.

4. The guide wire according to claim 3, wherein at least a portion of said coating (32) at said distal end portion (30B) is smaller in cross-section than at said body portion (30A).

5. The guide wire according to claim 3, wherein said coating (32) has substantially equal outer diameters at the distal end portion (30B) and at the body portion (30A).

6. The guide wire according to any one of claims 3 to 5, wherein a portion of the inner core (31C) is progressively reduced in cross-section from the body portion (30A) toward the distal end portion (30B).

7. The guide wire according to any one of the preceding claims, wherein the body portion (30A) has a yield stress of 10 to 80 kg/mm^2, and in that the distal end portion (30B) has a yield stress of 18 to 24 kg/mm^2.

Patentansprüche

1. Führungsdraht für einen Katheter mit einem Rumpfabschnitt (11) und einem distalen Endabschnitt (12), wobei zumindest ein Abschnitt des distalen Endabschnitts (12) einen geringeren Querschnitt aufweist als der Rumpfabschnitt (11), der eine vergleichsweise hohe Steifigkeit besitzender distale Endabschnitt (12) vergleichsweise biegsam ist,
dadurch gekennzeichnet, daß
der Rumpfabschnitt (11) und der distale Endabschnitt (12) aus einem superelastischen Metallteil bestehen.

2. Führungsdraht nach Anspruch 1,
dadurch gekennzeichnet, daß
ein Zwischenabschnitt (13), der zwischen dem Rumpfabschnitt (11) und dem distalen Endab-

schnitt (12) liegt, ausgehend vom Rumpfabschnitt (11) zum distalen Endabschnitt (12) hin im Querschnitt zunehmend verringert ist.

3. Führungsdraht für einen Katheter mit einem Innenkern (31), der mit einem Kunststoffüberzug (32) aus Plastik überzogen ist,
wobei er einen Rumpfabschnitt (30A) und einen distalen Endabschnitt (30B) aufweist, wobei zumindest ein Abschnitt des Innenkerns (31B) innerhalb des distalen Endabschnitts einen geringeren Querschnitt aufweist als der Innenkern (31A) innerhalb des Rumpfabschnitts, der eine Rumpfabschnitt vergleichsweise hohe Steifigkeit besitzt, und der distale Endabschnitt (30B) vergleichsweise biegsam ist,
dadurch gekennzeichnet, daß
der Innenkern (31A, 31B) sowohl innerhalb des Rumpfabschnitts als auch innerhalb des distalen Endabschnitts aus einem superelastischen Metallteil gebildet ist.

4. Führungsdraht nach Anspruch 3,
wobei wenigstens ein Abschnitt des Überzugs (32) am distalen Endabschnitt (30B) einen geringeren Querschnitt als am Rumpfabschnitt (30A) aufweist.

5. Führungsdraht nach Anspruch 3,
wobei der Überzug (32) am distalen Endabschnitt (30B) und am Rumpfabschnitt (30A) im wesentlichen gleiche Außendurchmesser aufweist.

6. Führungsdraht nach einem der Ansprüche 3 bis 5,
wobei ein Abschnitt des Innenkerns (31C) ausgehend vom Rumpfabschnitt (30A) hin zum distalen Endabschnitt (30B) im Querschnitt zunehmend verringert wird.

7. Führungsdraht nach einem der vorhergehenden Ansprüche,
wobei der Rumpfabschnitt (30A) eine Streckspannung von 10 bis 80 kg/mm^2 und der distale Endabschnitt (30B) eine Streckspannung von 18 bis 24kg/mm^2 aufweist.

Revendications

1. Fil de guidage pour un cathéter, comportant une partie corps (11) et une partie terminale distale (12), au moins une portion de ladite partie terminale distale (12) ayant une section droite plus petite que celle de la partie corps (11) qui a une rigidité relativement élevée, ladite partie terminale distale (12) étant relativement flexible, caractérisé en ce que ladite partie corps (11) et ladite partie terminale distale (12) sont formées toutes deux par un élément métallique superélastique.

2. Fil de guidage selon la revendication 1, dans lequel une partie intermédiaire (13) entre ladite partie corps (11) et ladite partie terminale distale (12) diminue progressivement de section depuis la partie corps (11) vers la partie terminale distale (12).

3. Fil de guidage pour un cathéter comportant une âme intérieure (31) qui est recouverte par un revêtement (32) en matière plastique, ce fil de guidage comportant une partie corps (30A) et une partie terminale distale (30B), au moins une partie de l'âme intérieure (31B) située dans la partie terminale distale ayant une section droite plus petite que celle de l'âme intérieure (31A) située dans la partie corps, ladite partie corps ayant une rigidité relativement élevée, la partie terminale distale (30B) étant relativement flexible, caractérisé en ce que l'âme intérieure (31A, 31B) à la fois dans la partie corps et dans la partie terminale distale est formée d'un élément métallique superélastique.

4. Fil de guidage selon la revendication 3, dans lequel au moins une partie dudit revêtement (32) située dans ladite partie terminale distale (30B) a une section droite plus petite que dans ladite partie corps (30A).

5. Fil de guidage selon la revendication 3, dans lequel ledit revêtement (32) a des diamètres extérieurs sensiblement égaux dans la partie terminale distale (30B) et dans la partie corps (30A).

6. Fil de guidage selon l'une quelconque des revendications 3 à 5, dans lequel une partie de l'âme intérieure (31X) diminue progressivement de section depuis la partie corps (30A) en direction de la partie terminale distale (30B).

7. Fil de guidage selon l'une quelconque des revendications précédentes, dans lequel la partie corps (30A) présente une limite élastique de 10 à 80 kg/mm^2 et en ce que la partie terminale distale (30B) présente une limite élastique comprise entre 18 et 24 kg/mm^2

FIG. 1

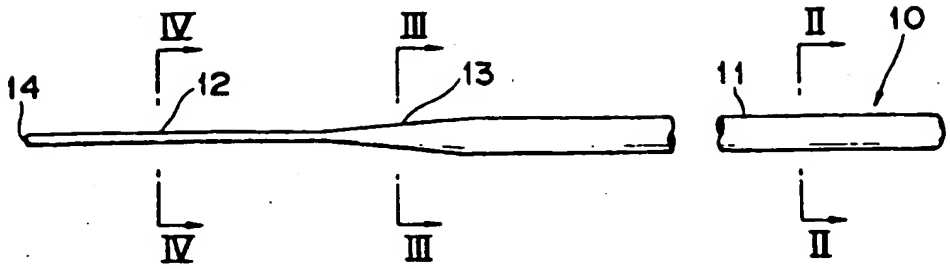
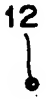


FIG. 2

FIG. 3

FIG. 4



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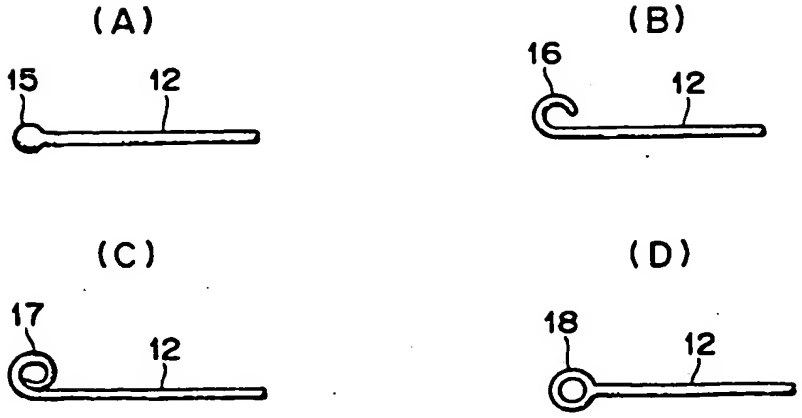

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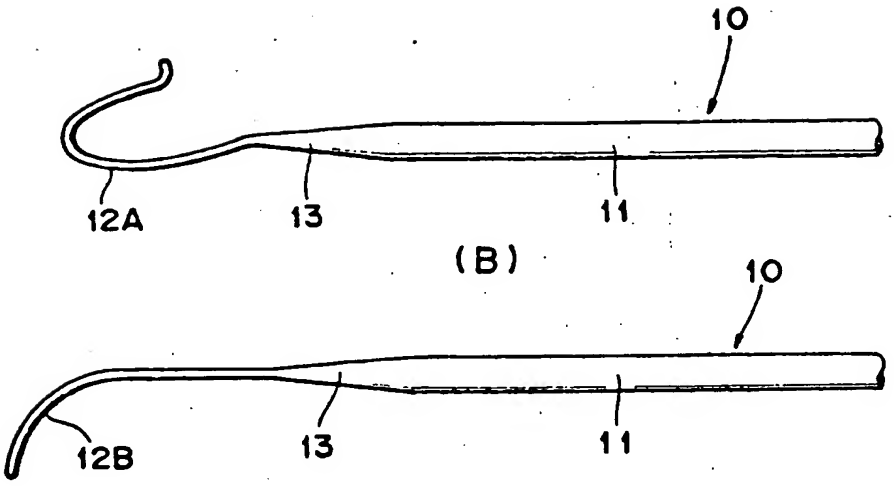

FIG. 7

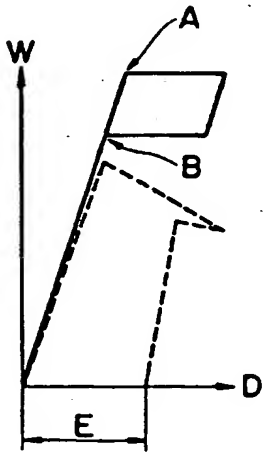

FIG. 8

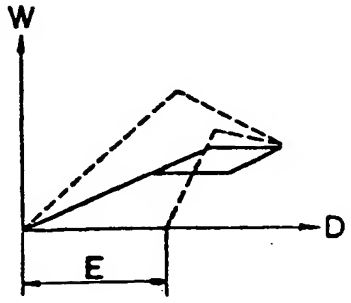

FIG. 9

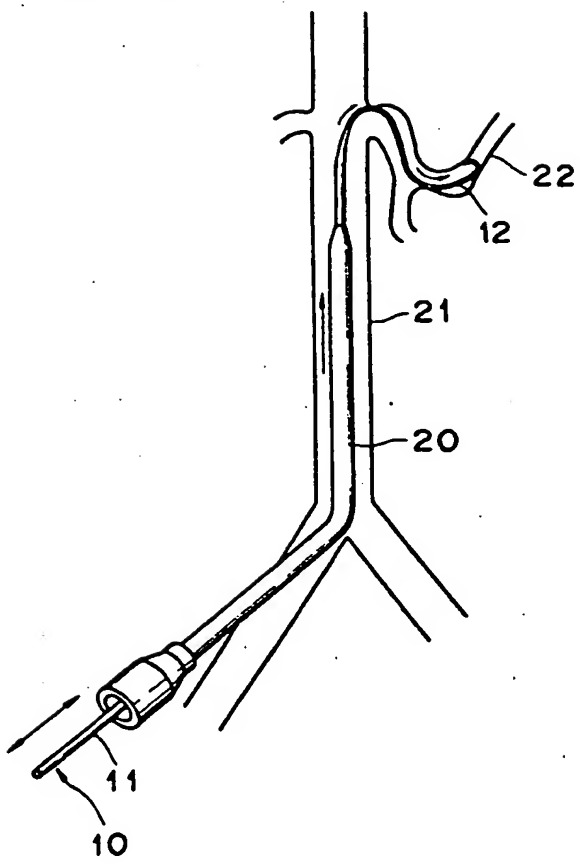
22
12
21
20
11
10

FIG. 10

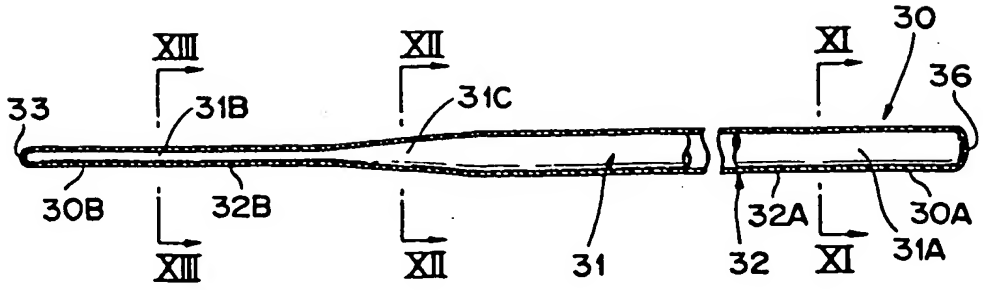
XIII
XII
XI
30
36
33
31B
31C
30B
32B
XIII
XII
31
32
XI
32A
30A
31A

FIG. 11

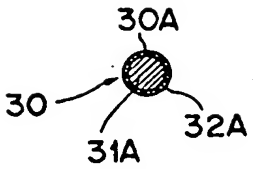

FIG. 12

FIG. 13

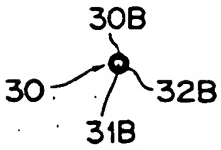

FIG. 14

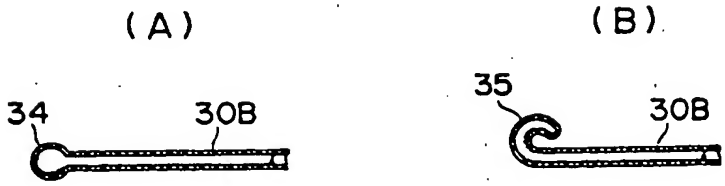

FIG. 15

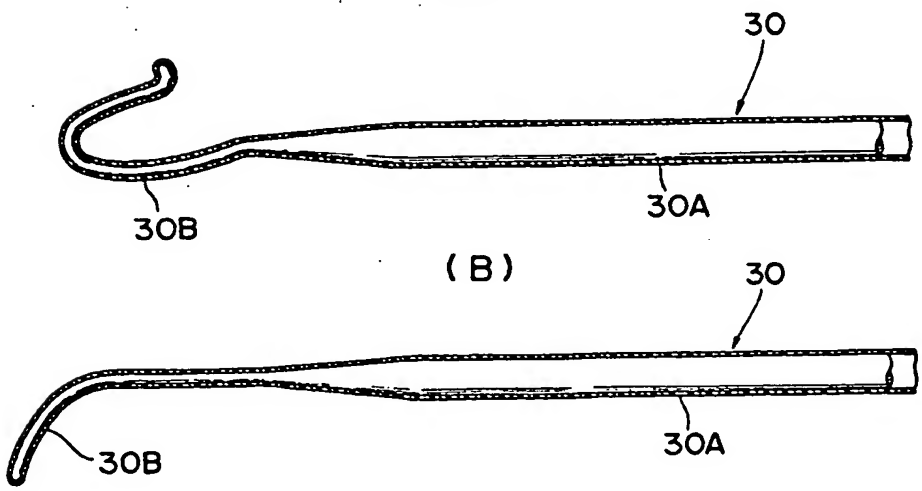

FIG. 16

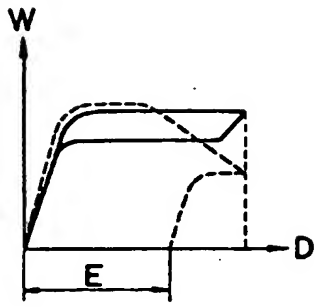

FIG. 17

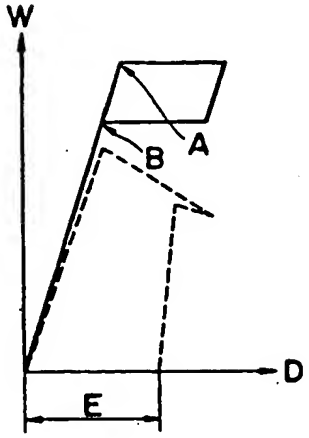

FIG. 18

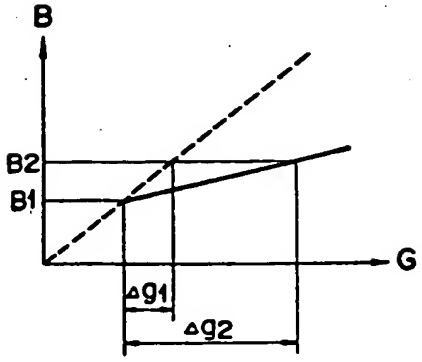

FIG. 19